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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/010,742

11/30/2001

Davin C. Dillon

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08/13/2004

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/010,742

Applicant(s)

DILLON ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,3 and 4.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

JEFFREY FREDMAN
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: it does not fully address the issues presented in the final rejection. Applicants provided a declaration of Dr. Davin Dillon, which states that: a) SEQ ID NO: 52 is 100% identical to SEQ ID NO: 305, therefore it is a partial sequence of SEQ ID NO: 305, therefore SEQ ID NO: 305 would be expected to have the same expression profile as SEQ ID NO: 52; b) real-time PCR showed that expression of SEQ ID NO: 305 was 10-100% higher in about 30% of breast tumors as compared to a panel of normal tissues; c) immunohistochemical analysis showed that the protein encoded by SEQ ID NO: 30 was present in both normal and breast cancer tissues.

There are several problems with this declaration. First, SEQ ID NO: 52 is only 379 bp long, whereas SEQ ID NO: 305 is 1518 bp long, therefore, SEQ ID NO: 52 could also be a part of a different splice variant which is overexpressed in breast cancer. Further, the term Applicants use for SEQ ID NO: 305, B854P, is not B854P, but a splice variant of B854P, denoted 228686-8 (specification, page 16, lines 3, 4). Therefore, if the overexpression of B854P was tested in various cells, it is not clear which splice variant was amplified, since Dr. Dillon did not provide any details of the amplified sequence and the primers used. Finally, Fig. 2 is not very informative for the purposes of demonstration that B854P is overexpressed in breast cancer tissue. First, the legend is illegible, therefore it is not possible to determine what cells were used. Even if it was, Dr. Dillon did not provide any details about the cells which were used in these tests, in particular, whether these cells were obtained directly from breast tumors or from cell lines. Finally, the immunohistochemical data is not relevant to the claims, since the claims are drawn to the nucleic acid, not to the protein.

FS

8/6/04